



K063072

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

Submitter Information

Company Name: Candela Corporation
Company Address: 530 Boston Post Road
Wayland, MA 01778
Company Phone: 508-358-7400
Company Facsimile: 508-358-5602
Contact Person: Mr. Jeffrey Roberts
Manager, Regulatory Affairs
Date summary Prepared: 10/05/06

DEC 20 2006

Device Identification

Device Trade/Proprietary Name: Candela Family of Q-Switched Alexandrite Laser
(Alex_{LAZR}) Systems: 532 and 1064 Nd:YAG Handpiece
Accessories
Common Name: Q-Switched Alexandrite Laser
Classification Name: Laser Surgical Instrument, for use in General and Plastic
Surgery and Dermatology
Classification Regulation: 21 CFR § 878.4810
Device Classification: II

Identification of Predicate Device

Predicate Device(s): Hoya ConBio, Inc., formerly Continuum Electro-Optics, Inc.
Medlite C3 Q-Switched Nd:YAG Laser, K011677
Candela Q-Switched, Frequency Doubled, Nd:YAG Laser
System, K942152
Candela Q-Switched Alexandrite Laser (Alex_{LAZR}), K955662

Device Description

The Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) systems: 532 Nd:YAG Handpiece Accessory consists of a cylindrical housing connecting to the distal end of the optical fiber which plugs into the standard Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) systems. The fiber carries the 755nm light from the Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) systems to the handpiece at the distal end where the wavelength conversion from 755nm to 532nm occurs. The principle of operation is outlined here. The 755nm light is focused by focusing lenses to a 2mm beam waist within an Nd:YAG rod situated in the heart of the converter module. It is known that Nd:YAG can be pumped at 755nm and made to lase at 1064nm with high efficiency. The Nd:YAG rod has two appropriately coated mirrors, one on either side, to form a laser resonator. Within the laser resonator is a Brewster Plate which

ensures that the output 1064nm beam is polarized (in another variation of the same scheme, the Nd:YAG will be replaced by Nd:YVO4 or similar gain medium which provides a naturally polarized output, eliminating the need for a Brewster Plate). The output of the Nd:YAG laser has the same pulse duration as the original 755nm laser, but the wavelength is now 1064nm. The 1064nm beam is then incident on a KTP crystal that is aligned for optimum phase matching for second harmonic generation at 532nm. The KTP crystal converts 1064nm to 532nm efficiently. A dichroic beam-splitter separates the 532nm beam from the residual unconverted 1064nm. The 532nm beam is appropriately shaped and sized using lenses and is incident on the skin during treatment. The unconverted 1064nm that is rejected by the beam-splitter is safely absorbed in a beam dump within the module.

The Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) systems: 1064 Nd:YAG Handpiece Accessory is very similar to the 532nm handpiece except that there is no KTP crystal for the 1064nm to 532nm conversion. The beam is extracted immediately after the Nd:YAG laser resonator.

Description of Intended Use

The Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) Systems: 532 and 1064 Nd:YAG Handpiece Accessories are indicated for the following uses:

Tattoo Removal

Treatment of Vascular Lesions

Treatment of Pigmented Lesions

Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology

Rationale for Substantial Equivalence

The Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) Systems: 532 and 1064 Nd:YAG Handpiece Accessories have the same intended use and utilizes similar functional features (including power output, spot size, repetition rate, energy, and fluence) and matches key design aspects (including wavelength, light generation medium, power supply, cooling and controls system) as the predicate devices.

The Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) Systems: 532 and 1064 Nd:YAG Handpiece Accessories shares similar methods of assembly, method of operation and intended uses, and therefore is substantially equivalent to the currently legally marketed Hoya ConBio Inc., Medlite C3 Q-Switched Nd:YAG Laser, K011677, Candela Q-Switched, Frequency Doubled, Nd:YAG Laser System, K942152, and Candela Q-Switched Alexandrite Laser (Alex_{LAZR}), K955662.

Safety and Effectiveness Information

The Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) Systems: 532 and 1064 Nd:YAG Handpiece Accessories are substantial equivalent to the currently legally marketed Hoya ConBio Inc., Medlite C3 Q-Switched Nd:YAG Laser, K011677, Candela Q-Switched, Frequency Doubled, Nd:YAG Laser System, K942152, and Candela Q-Switched Alexandrite Laser (Alex_{LAZR}), K955662 predicate devices in intended use and technological features and therefore the risks and benefits are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) Systems: 532 and 1064 Nd:YAG Handpiece Accessories.

Conclusion

Base on the similarities in indications for use, design features, and functional features Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) Systems: 532 and 1064 Nd:YAG Handpiece Accessories have been shown to be substantially equivalent to the current legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2006

Candela Corporation
% Mr. Jeffrey Roberts
Manager, Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K063072

Trade/Device Name: Candela Family of Q-Switched Alexandrite Laser (Alex_{LAZR}) systems:
532 and 1064 Nd:YAG Handpiece Accessories

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: October 5, 2006

Received: October 10, 2006

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

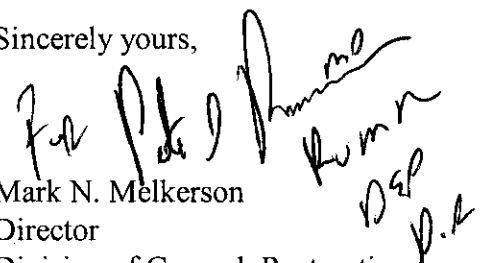
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063072

Device Name: Candela Family of Q-Switched Alexandrite Laser (AlexLAZR) systems: 532 and 1064 Nd:YAG Handpiece Accessories

Indications for Use:

The Candela Family of Q-Switched Alexandrite Laser (AlexLAZR) systems: 532 and 1064 Nd:YAG Handpiece Accessories are indicated for the following uses:

Tattoo Removal

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Treatment of Pigmented Lesions

Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

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